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<p>(21) International Application Number: PCT/AU97/00450</p> <p>(22) International Filing Date: 16 July 1997 (16.07.97)</p> <p>(30) Priority Data: PO 1265 26 July 1996 (26.07.96) AU</p> <p>(71) Applicant (for all designated States except US): RESMED LIMITED [AU/AU]; 82 Waterloo Road, North Ryde, NSW 2113 (AU).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): KWOK, Philip, Rodney [AU/AU]; 7 Apollo Avenue, West Pymble, NSW 2073 (AU). STYLES, Robert, Edward [AU/AU]; 35 Linksley Avenue, Glenhaven, NSW 2156 (AU).</p> <p>(74) Agent: SPRUSON & FERGUSON; G.P.O. Box 3898, Sydney, NSW 2001 (AU).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>	
<p>(54) Title: A NASAL MASK AND MASK CUSHION THEREFOR</p> <p>(57) Abstract</p> <p>A nasal cushion (30) comprises a substantially triangularly shaped frame (32) from which extends a membrane (34). The frame (32) has a scalloped edge (36) by which the cushion (30) is affixed to a mask body. The membrane (34) has an aperture (38) into which the wearer's nose is received. The membrane (34) is spaced away from the rim (40) of the frame (32), and its outer surface (41) is of substantially the same shape as the rim (40). Respective notches (42, 44) receive the bridge of the wearer's nose. The wearer's nose is received through the aperture (38) into the chamber within the mask body (46). The seal forming portion (45) thus contacts both the surface of the wearer's nose and a portion of the wearer's face in the region between the base of the nose and the upper lip, and around the sides and over the bridge of the nose. The shape of the seal forming portion (45) is particularly suited to effectively seal the difficult region of the facial contour that is the crease between the sides of the nose and the face.</p>			

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A NASAL MASK AND MASK CUSHION THEREFOR

Field of the Invention

The invention relates generally to a nasal mask and to a cushion therefor, for 5 example, for use in the treatment of respiratory conditions and in assisted respiration.

Background of the Invention

Nasal masks are commonly used in the treatment of respiratory conditions and sleep disorders (e.g., obstructive sleep apnea) by delivering a flow of breathable gas 10 for, or to assist patient respiration. These nasal masks typically receive a gas supply line which delivers gas into a chamber formed by walls of the mask. The walls usually are semi-rigid and have a face contacting portion including an aperture which is aligned with the wearer's nostrils. The face contacting portion can comprise a soft, resilient elastomeric material which may conform to various facial contours. The mask 15 normally is secured to the wearer's head by straps. The straps are adjusted to pull the mask against the face with sufficient force to achieve a gas tight seal between the mask and the wearer's face. Gas is thus delivered to the mask and through the aperture to the wearer's nasal passages.

Problems often arise with masks of the above configuration. For example, the 20 mask may be dislodged, thereby breaking the seal between the mask and wearer. This may occur if the wearer rolls over when sleeping thereby creating a drag force on the gas supply line which is transmitted to the mask, breaking the seal. In the case of a mask being used for the administration of Continuous Positive Airway Pressure (CPAP) treatment for the condition obstructive sleep apnea, such a leak can result in the 25 pressure supplied to the entrance of the wearer's airway being below the therapeutic value, and the treatment becoming ineffective.

Another problem is that the face contacting portion may apply excessive pressure to the wearer's face resulting in discomfort and possibly skin irritation. This

excessive forces. In some cases these excessive pressures and forces may cause the face to distort to conform with the face contacting portion to increase wearer discomfort, facial soreness and ulceration.

Other types of devices exist whereby small nostril nosepieces (pillows) are held

5 in place by a harness strapped over the wearer's head, for example as shown in prior art U.S. Patent No. 4,782,832. While this arrangement may alleviate some problems regarding seal breakage and skin abrasion, the harnesses associated with such devices are quite cumbersome for the wearer, as are the gas supply lines. Also, air 'jetting' into the nostrils can be irritating to the patient making such devices generally

10 uncomfortable to use.

In Figs. 1-3, a prior art nasal cushion 10, generally equivalent to that shown in prior art U.S. Patent No. 5,243,971, is first described.

As shown, the cushion 10 generally includes a base 11 from which depends a semi-rigid cushion frame 12 formed of elastomeric material. Attached over the outside

15 of the frame 12 is a membrane 15, also of elastomeric material, having at its distal end a face contacting portion 14. The frame 12 and the membrane 15 generally form a chamber 17 into which the wearer's nose can be received. The frame 12 has a notch 19 to accommodate the bridge of the wearer's nose. The base 11 includes slots 13 to accommodate straps (not shown) to secure the cushion 10 and a mask body (not shown)

20 in combination to the wearer's head.

An aperture 16 is formed at the end of the membrane 15 distal from the frame 12 providing access for a wearer's nose 20 to the chamber 17 as noted. As shown, the aperture 16 in an unflexed state is generally circular (or elliptical) and is large enough to allow partial entry of the wearer's nose. The resilience of the membrane material

25 allows the face contacting portion 14 and the aperture 16 to invert when the nose is received. The inverted membrane arrangement relies upon a positive pressure of supplied gas within the mask to effect a seal to the wearer's face. The seal is characterised as a "rolling edge seal", in that there can be motion of the cushion 10

relative to the patient's face yet the seal is maintained. Even so, a tuck 22 arises in the vicinity of the upper lip due to the circular shape of the aperture, and it is from this tuck that leaks can arise due to head and body movement during sleep.

It is an object of the invention to overcome or at least substantially ameliorate
5 one or more of the foregoing disadvantages.

Summary of the Invention

In one broad form, the invention discloses a nasal mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising:

10 a substantially triangularly-shaped frame of resilient material having a rim to surround the wearer's nose;
a membrane also of resilient material, the membrane being relatively more flexible than the frame, and being of the same general shape as said rim and fixed to and extending away from the frame so as to have an outer surface spaced from the rim,
15 a portion of said outer surface forming a face contacting seal; and
a nose-receiving cavity bounded by said frame and said membrane;
and wherein said seal portion is generally coterminous with respect to said rim and is resiliently deformable towards the rim in use of the cushion.

Preferably, the rim and seal portion are shaped to generally match facial
20 contours of the facial tissue around the sides and over the bridge of the nose and between the base of the nose and the top lip.

In one particularly advantageous form, the membrane is substantially saddle-shaped. The membrane further has a centrally located aperture through which the wearer's nose passes to enter said cavity.

25 It is preferred that the cushion and membrane each include a co-located notch to accommodate the bridge of the nose of the wearer. Typically, the seal portion contacts at least the wearer's nose, and preferably, also the facial tissue around the sides and over the bridge of the nose and between the base of the nose and the top lip.

The invention further discloses a nasal mask for connection to a wearer's face comprising:

- a mask body for connection with a supply of breathable gas; and
- a nasal cushion, the body and cushion defining a nose-receiving cavity, the

5 cushion including:

- a substantially triangularly-shaped frame of resilient material having a rim to surround the wearer's nose;
- a membrane also of resilient material, the membrane being relatively more flexible than the frame, and being of the same general shape as said rim and fixed to

10 and extending away from the frame so as to have an outer surface spaced from the frame, a portion of said outer surface forming a face contacting seal;

- and wherein said seal portion is generally coterminous with respect to said rim and is resiliently deformable towards the rim in use of the mask.

The mask body can further include attachment points from which securing straps can be attached, and by which the mask can be secured to the wearer's head. The nasal mask can yet further comprise an arm depending from said body from which a further securing strap(s) can be attached.

The invention further discloses nasal CPAP treatment apparatus comprising a flow generator for the supply of gas at a pressure elevated above atmospheric pressure

20 to a gas delivery conduit, the conduit in turn coupled to a nasal mask as described immediately above.

In one particularly preferred form, a supply of gas can be provided to said cavity, said supply of gas assisting, but not solely causing maintenance of a seal by said seal forming portion of said membrane to the face of the wearer in use of the cushion.

25 Advantageously, because the membrane and the rim are substantially shaped to the facial contour, and the membrane does not need to turn in on itself, as in the prior art, thus contacting the face without folds or creases. With the cushion/mask secured to the wearer's head, the headstraps need only to be tensioned to balance the force due to

mask gas pressure that tends to lift the mask off the face. Such relatively lower mask-to-face pressure results in greater patient comfort, and a reduction in the likelihood of skin irritation.

5 Brief Description of the Drawings

An embodiment of the invention will now be described with reference to the accompanying drawings, in which:

Fig. 1 is an exploded perspective view of a prior art nasal mask;
Fig. 2 is a perspective view of the prior art nasal mask of Fig. 1;
10 Fig. 3 is a perspective view of the prior art nasal mask attached to a wearer;
Fig. 4 is a rear perspective view of a mask cushion embodying the present invention;

Fig. 5 is a cross-sectional view along line 5-5;
Fig. 6 is a perspective view of a nasal mask including the cushion of Figs. 4
15 and 5; and

Fig. 7 is a perspective view of the nasal mask of Fig. 6 secured to a wearer's head.

Description of the Preferred Embodiments

20 Fig. 4 shows a perspective view of a nasal cushion 30 embodying the invention. Fig. 5 shows the cross-sectional view along line 5-5. The cushion 30 comprises a substantially triangularly shaped frame 32 from which extends a membrane 34. The frame 32 has a scalloped edge 36 by which the cushion 30 is affixed to a mask body, as presently will be described.

25 The membrane 34 has an aperture 38 into which the wearer's nose is received in use of the cushion 30. The membrane 34 is spaced away from the rim 40 of the frame 32, and its outer surface 41 is of substantially the same shape as the rim 40. The outer surface 41 of the membrane 34 and the rim 40 of the frame 32 also can be

described as generally saddle shaped. The shaping of the outer surface 41 of the membrane 34 and the rim 40 of the frame 32 also include respective notches 42,44 that receive the bridge of the wearer's nose in use of the cushion 30.

As is best seen in Fig. 5, the frame 32 and the membrane 34 are integrally formed, typically by in a one-shot molding process. The frame 32 and the membrane 34 are fabricated from a resilient material. One suitable such material is Silastic™ silicone elastomer manufactured by Dow Corning. The frame 32, in one preferred embodiment, has a typical thickness at its rim 40 of 1.5 mm. The membrane 34, in a preferred embodiment, has a typical thickness of 0.35 mm. In this way, the membrane 10 34 is relatively more flexible than the rim 40.

In use of the cushion 30, a wearer's nose will be inserted in the aperture 38 to engage a seal forming portion 45 (formed between the dashed lines) of the outer surface 41 to cause deformation of the membrane 34. Depending upon the securing force supplied to the membrane 34, it may deform to a point where it butts against the rim 40 15 of the frame 32. The frame 32 has a rigidity sufficient to withstand usual securing pressures in use of the cushion 30 to tend to retain its shape and resist deformation. It thus acts as a supporting structure.

Referring now to Fig. 6, the nasal cushion 30 is shown attached to a mask body 46 by the edge 36 of the frame 32, adhered or otherwise secured to a flange 48 of 20 the mask body 46. Only the outer surface 41 of the membrane 34 can be seen. The flange 48 includes three slots 50-54 from which tensioning straps can be attached to secure the cushion 30 and the mask body 46 (in combination) to the head of a wearer.

The mask body 46 forms a cavity that can receive the nose of the wearer by the aperture 38. A port 56 is provided at the top of the mask body 46 by which 25 breathable gas can be supplied to the chamber.

Referring now to Fig. 7, there is shown a nasal mask 60 including the mask body 46 and the mask cushion 30. A coupling tube 62 is connected at one end with the inlet port 56, and at the other to a socket 64 into which can be received a gas delivery

tube (not shown) for the supply of breathable gas to the chamber internal of the mask body 46. The mask body 46 also has two vent openings 66 by which expired gas is exhausted. A first fastening strap 68 is fixed between the lower two slots 50,54. The upper slot 52 receives an arm 70, the top end of which has a resilient pad 72 to engage the forehead of the wearer. The arm 70 has two slots 74,76 along its side edges, by which a second fastening strap 78 is secured.

5 In fitting the nasal mask 60, the wearer's nose is received through the aperture 38 into the chamber within the mask body 46. The seal forming portion 45 thus contacts both the surface of the wearer's nose and a portion of the wearer's face in the 10 region between the base of the nose and the upper lip, and around the sides and over the bridge of the nose. The shape of the seal forming portion 45 is particularly suited to effectively seal the difficult region of the facial contour that is the crease between the sides of the nose and the face. Depending upon the tension applied by the fastening straps 68,78, a seal is formed with the membrane 34 remaining spaced from the rim 40 15 of the cushion frame 32. While the provision of pressurised gas to the chamber of the mask body 46 assists in the maintenance of a seal between the membrane 34 and the wearer's nose and face, it is not essential in most cases, and an effective seal will be formed absent any such pressurised gas. The seal formed between the membrane 34 and the wearer's nose and face is not in the nature of a rolling seal in the manner of 20 prior art as shown in Figs. 1 to 3, as on relative movement of the mask 60 in relation to the wearer's head, the nose will be restrained by contacting the frame 32. Thus only limited relative motion between the mask 60 and the wearer's nose and face occurs.

25 The membrane 34 closely imitates the facial contour, and because of its relatively lesser stiffness than the frame 32, can conform to particular facial structures with minimum force, and without a tendency to fold or crease.

If the fastening strap 68,78 are tensioned to excess, the membrane 34 deforms to abut the rim 40 of the cushion 32, the frame 32 thus acting as an "end limit". In

such a configuration, almost zero relative movement can occur between the mask 60 and the wearer's head.

The nasal cushion 30 and nasal mask 60 has been described with reference to CPAP or assisted respiration treatment, however it is to be understood that the

5 invention generally is applicable to any application where gas and/or atomised liquid is to be supplied to the entrance of the nasal airways. Such applications include nebulisers, gas masks and anaesthetic machines.

Claims:

1. A nasal mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising:
 - a substantially triangularly-shaped frame of resilient material having a rim to surround the wearer's nose;
 - a membrane also of resilient material, the membrane being relatively more flexible than the frame, and being of the same general shape as said rim and fixed to and extending away from the frame so as to have an outer surface spaced from the rim, a portion of said outer surface forming a face contacting seal; and
 - 10 a nose-receiving cavity bounded by said frame and said membrane; and wherein said seal portion is generally coterminous with respect to said rim and is resiliently deformable towards the rim in use of the cushion.
2. A nasal cushion as claimed in claim 1, wherein said membrane and said rim each has a co-located notch to accommodate the bridge of a nose.
3. A nasal cushion as claimed in claim 1 or claim 2, wherein said membrane and said rim are substantially saddle-shaped.
- 20 4. A nasal cushion as claimed in claim 3, wherein said membrane is shaped so that said seal portion, in use, contacts at least a wearer's nose.
5. A nasal cushion as claimed in claim 4, wherein said seal portion, in use, contacts the facial tissue around the sides and over the bridge of the nose, and 25 between the base of the nose and the top lip.

- 10 -

6. A nasal cushion as claimed in claim 1, wherein said rim and said seal portion are shaped to generally match facial contours of the facial tissue around the sides and over the bridge of the nose, and between the base of the nose and the top lip.

5 7. A nasal mask for connection to a wearer's face comprising:

a mask body for connection with a supply of breathable gas; and

a nasal cushion, the body and cushion defining a nose-receiving cavity, the cushion including:

a substantially triangularly-shaped frame of resilient material having a rim to

10 surround the wearer's nose;

a membrane also of resilient material, the membrane being relatively more flexible than the frame, and being of the same general shape as said rim and fixed to and extending away from the frame so as to have an outer surface spaced from the frame, a portion of said outer surface forming a face contacting seal;

15 and wherein said seal portion is generally coterminous with respect to said rim and is resiliently deformable towards the rim in use of the mask.

8. A nasal mask as claimed in claim 7, wherein said mask body includes attachment points.

20

9. A nasal mask as claimed in claim 8, further comprising securing straps fixed to said attachment points.

10. A nasal mask as claimed in claim 9, wherein said membrane and said 25 rim each has a co-located notch to accommodate the bridge of a nose.

11. A nasal mask as claimed in claim 10, wherein said membrane and said rim are substantially saddle-shaped.

12. A nasal mask as claimed in claim 11, wherein said membrane is shaped so that said seal portion, in use, contacts at least a wearer's nose.

5 13. A nasal mask as claimed in claim 12, wherein said seal portion, in use, contacts the facial tissue around the sides and over the bridge of the nose, and between the base of the nose and the top lip.

10 14. A nasal mask as claimed in any one of claims 7, 8 or 9, wherein said rim and said seal portion are shaped to generally match facial contours of the facial tissue around the sides and over the bridge of the nose, and between the base of the nose and the top lip.

15 15. Nasal CPAP treatment apparatus comprising:
a flow generator for the supply of gas at a pressure elevated above atmospheric pressure;
a gas delivery conduit coupled to said flow generator; and
a nasal mask in turn coupled to said conduit to said nasal mask including:
a mask body for connection with a supply of breathable gas; and
20 a nasal cushion, the body and cushion defining a nose-receiving cavity, the cushion including:
a substantially triangularly-shaped frame of resilient material having a rim to surround the wearer's nose;
a membrane also of resilient material, the membrane being relatively more flexible than the frame, and being of the same general shape as said rim and fixed to and extending away from the frame so as to have an outer surface spaced from the frame, a portion of said outer surface forming a face contacting seal;

and wherein said seal portion is generally coterminous with respect to said rim and is resiliently deformable towards the rim in use of the mask.

16. CPAP treatment apparatus as claimed in claim 15, wherein said mask
5 body includes attachment points.

17. CPAP treatment apparatus as claimed in claim 16, wherein further comprising securing straps fixed to said attachment points.

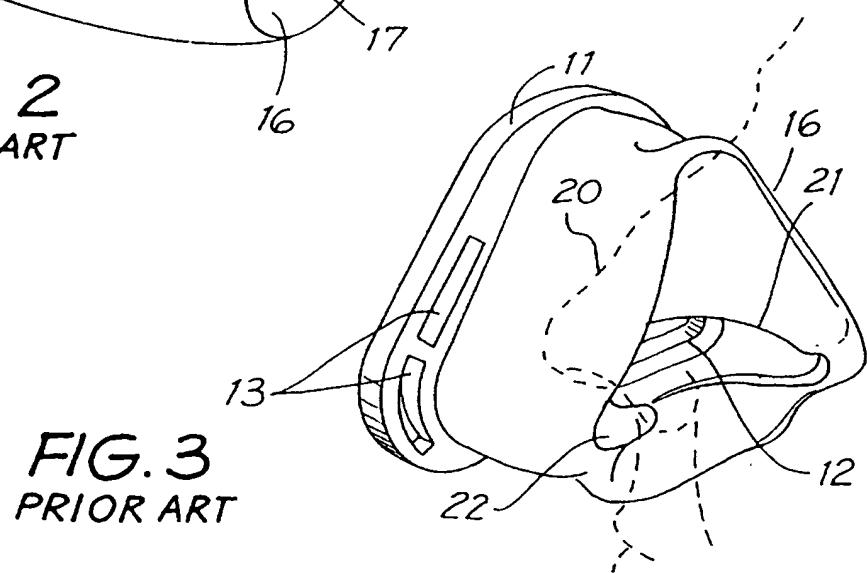
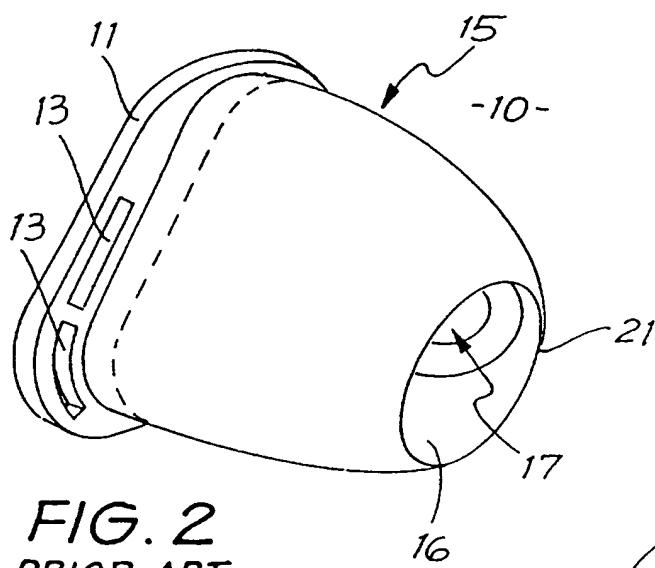
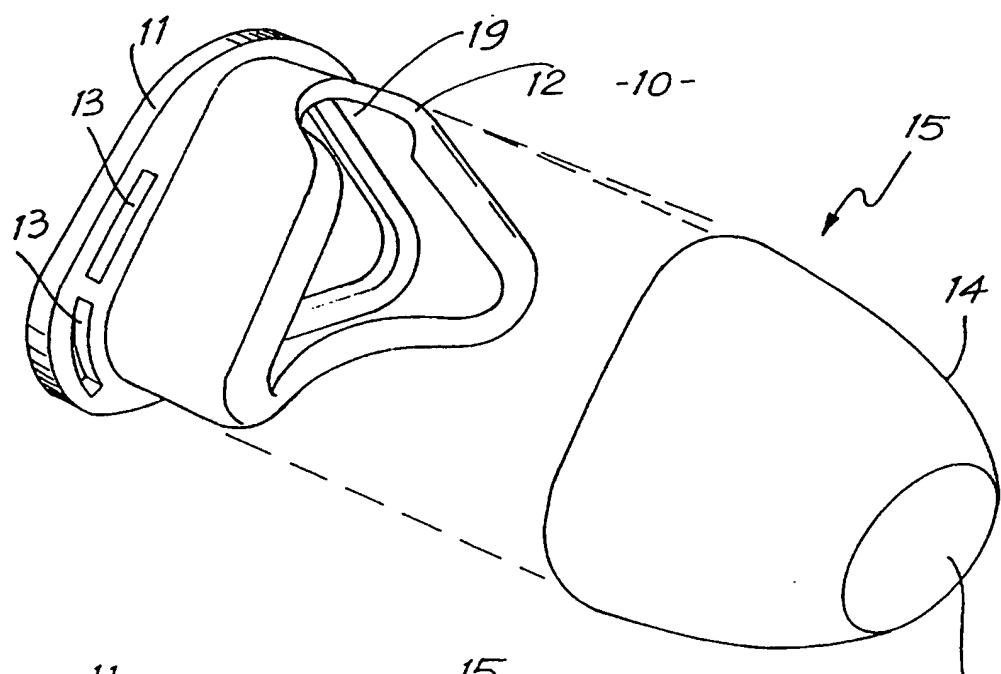
10 18. CPAP treatment apparatus as claimed in claim 17, wherein said membrane and said rim each has a co-located notch to accommodate the bridge of a nose.

19. CPAP treatment apparatus as claimed in claim 18, wherein said
15 membrane and said rim are substantially saddle-shaped.

20. CPAP treatment apparatus as claimed in claim 19, wherein said membrane is shaped so that said seal portion, in use, contacts at least a wearer's nose.

20 21. CPAP treatment apparatus as claimed in claim 20, wherein said seal portion, in use, contacts the facial tissue around the sides and over the bridge of the nose, and between the base of the nose and the top lip.

22. CPAP apparatus as claimed in any one of claims 15, 16 or 17 wherein
25 said rim and said seal portion are shaped to generally match facial contours of the facial tissue around the sides and over the bridge of the nose, and between the base of the nose and the top lip.



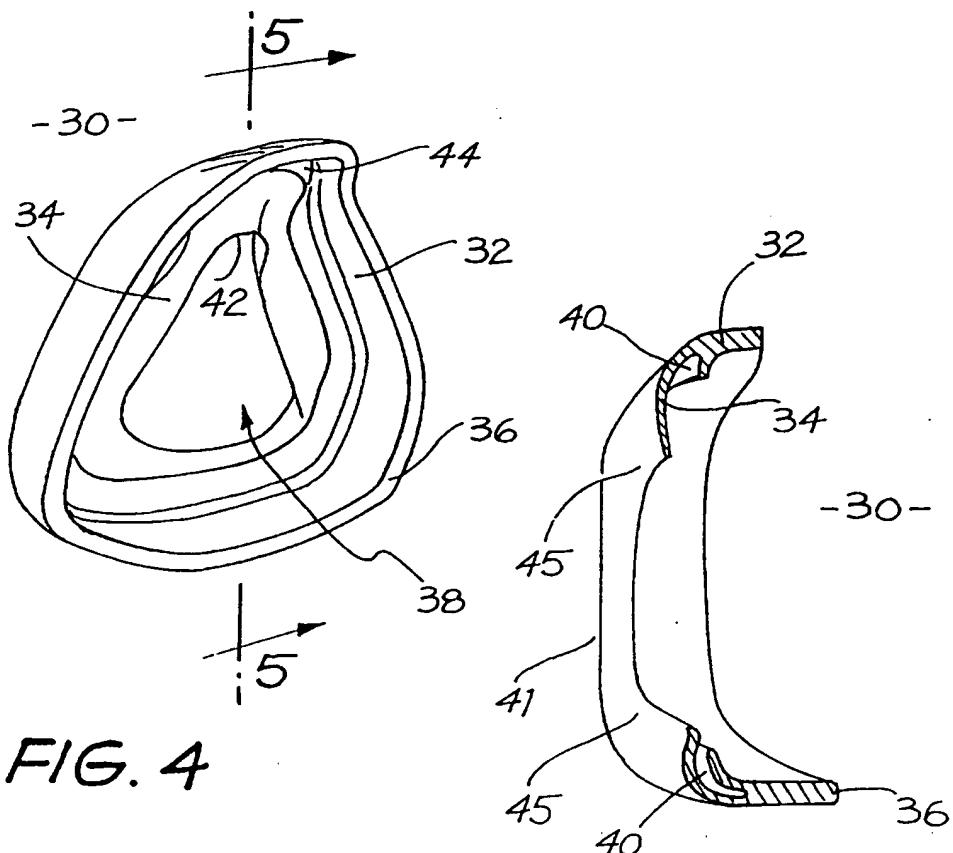


FIG. 4

FIG. 5

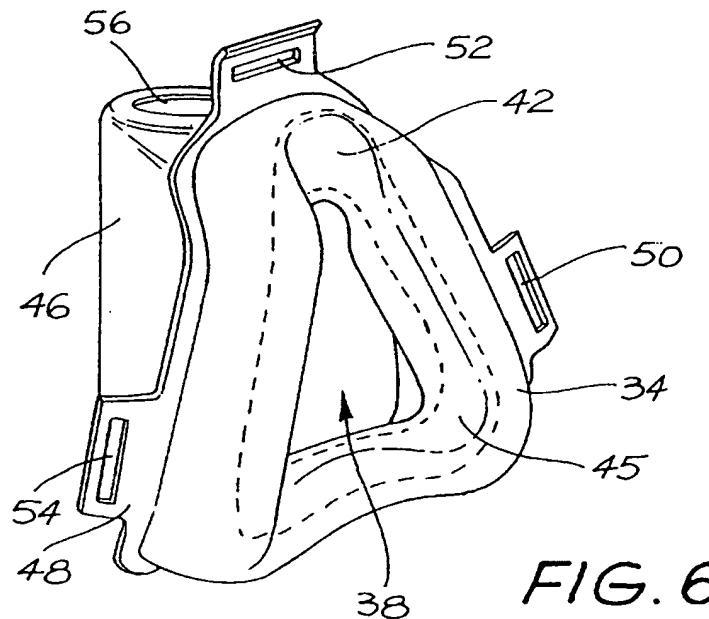


FIG. 6

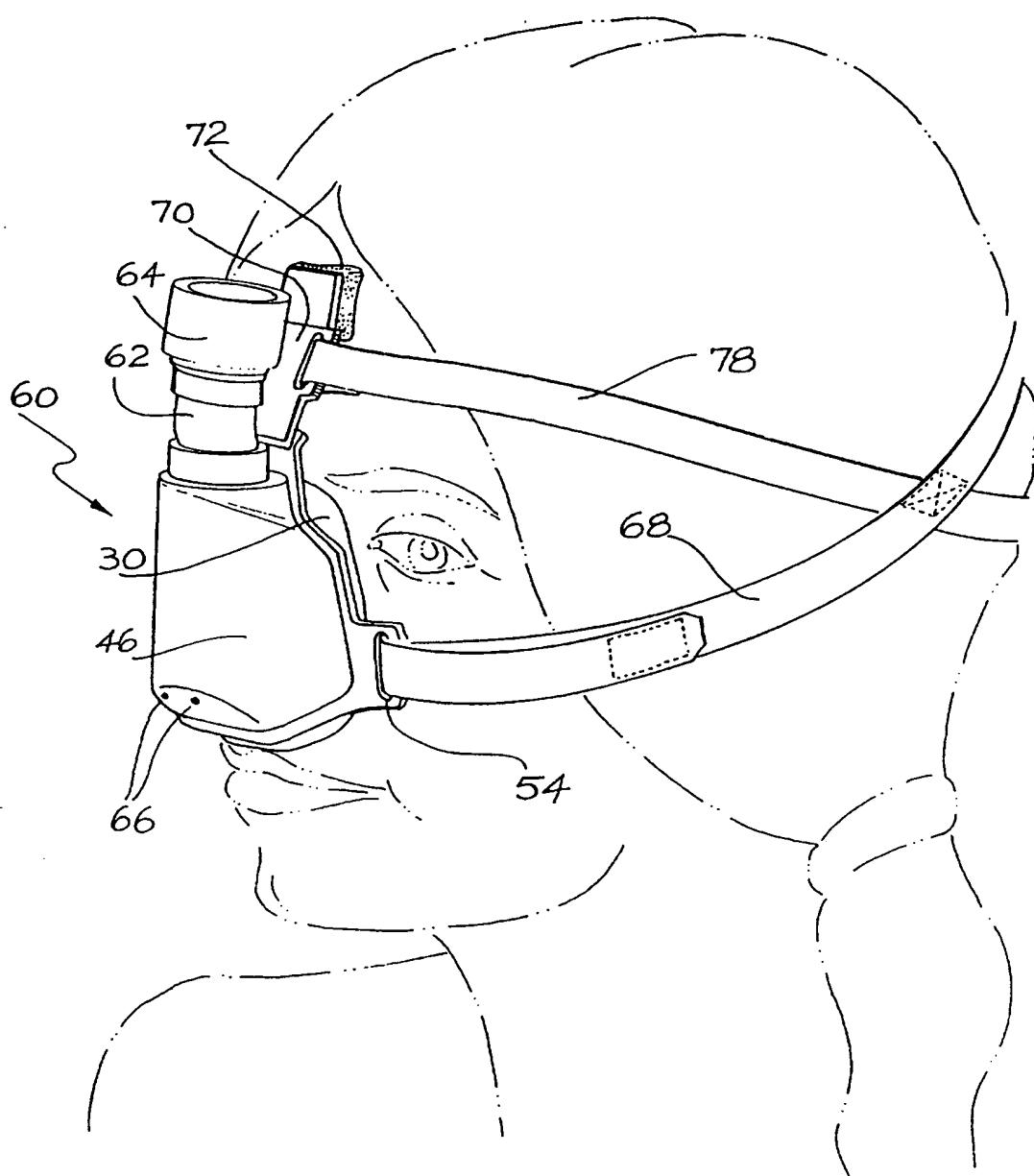
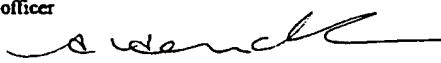


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00450

A. CLASSIFICATION OF SUBJECT MATTER		
Int Cl ⁶ : A61M 16/06		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT : Mask: Nasal: Nose: Nostril: Cushion: Seal: Rim: JAPIO : Air(W) Tight Gas(W)Tight		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP, A1, 0264772 (American Cyanamid Company) 27 April 1988 Figures 1A to 1D and 4; Columns 4-5	1-22
A	US 4402316 (Gadberry) 6 September 1983 Figures 10, 12, item 80	
A	US 4907584 (McGinnis) 13 March 1990 see Columns 6 to 8	
<input type="checkbox"/> Further documents are listed in the continuation of Box C		<input checked="" type="checkbox"/> See patent family annex
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Date of the actual completion of the international search 10 September 1997		Date of mailing of the international search report 18 SEP 1997
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929		Authorized officer  A.R. HENDRICKSON Telephone No.: (02) 6283 2415

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No.
PCT/AU 97/00450

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Patent Document Cited in Search Report			Patent Family Member		
EP	0264772	CA	1280334	US	4739755
US	4402316				
US	4907584				